UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

MARY VEGA and MARCELO VEGA, Plaintiffs, v. DAVOL, INC. and C.R. BARD, INC. Defendants,	Court File No. 08cv6252 JMR/JSM **COMPLAINT** **Jury Trial Demanded**

Plaintiffs, by their attorney, bring this action, and for their Complaint (hereinafter "Complaint"), allege the following upon information and belief:

NATURE OF THE ACTION

1. Plaintiffs bring this action against C.R. Bard, Inc. ("Bard") and its wholly owned subsidiary, Davol, Inc., ("Davol"), for their sale and distribution of defective Composix Kugel Mesh Patches. Defendants' defective product has been surgically implanted into the body of Plaintiff.

2. The patches present, and will continue to present, substantial risk of injury or death to Plaintiff. As a result, Plaintiffs have been injured and will need continual and ongoing medical monitoring. Additionally, Plaintiffs bring a claim for economic damages incurred for the purchase of the relevant defective products.

PARTIES

3. Plaintiff Mary Vega ("Plaintiff") is an individual citizen and resident of the State of Minnesota. In September 2005, Plaintiff had a hernia repair surgery which included the implantation of a Composix Kugel Mesh Patch into her body. Ms. Vega suffered severe pain and

numerous medical problems from the Kugel Mesh. She was hospitalized in February 2008 for removal of the disrupted Kugel Mesh Patch.

4. Defendant Davol, Inc., (hereinafter "Davol") is and was a wholly owned subsidiary of Bard, with its principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island, 02886. Davol's registered agent in Rhode Island is CT Corporation System located at 10 Weybosset Street, Providence, Rhode Island 02903. At all times relevant, Davol was a corporation duly organized and existing under the laws of the State of Delaware.

5. Davol designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products, including the Composix Kugel Mesh Hernia Patch, to be surgically implanted in patients throughout the United States, including Minnesota.

6. Defendant Bard is a New Jersey corporation with its principal office and place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, and at all times relevant designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including Minnesota. Bard manufactures and supplies Davol with material that forms part of the Composix Kugel Mesh Patch.

7. Upon information and belief, and at all times relevant, Bard sells the Composix Kugel Mesh Patch through its wholly-owned subsidiary, Davol.

8. Upon information and belief, Davol and Bard (hereinafter referred to collectively as "Defendants") transacted or conducted business in and have derived substantial revenue from goods and products used in every State or Territory in the United States.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and Defendants.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants researched, designed, licensed, manufactured, tested, marketed, distributed, and/or sold the Kugel Mesh Patches within this judicial district and because defendants are subject to personal jurisdiction within this states. Defendants earn substantial compensation and profits from sales of Kugel Mesh Patches in this District.

FACTUAL BACKGROUND

11. This action involves the Composix Kugel Mesh Patch manufactured by Defendants between 2001 and January 2007. These Composix Kugel Mesh Patches were sold by Defendants for implantation in patients in the course of hernia repair surgery.

12. Upon information and belief, from 2004-2006 alone, Defendants had sales from their Surgical Specialties segment of business, which includes the Composix Kugel Mesh Patch, of roughly one billion dollars ($1,000,000,000).

13. A hernia is a protrusion of an organ or tissue through an abnormal opening in the body. Hernias occur when a piece of intestine slips through a weakness in the abdominal wall,

creating a bulge you can see and feel. Hernias can develop around the navel, in the groin or any place where you may have had a surgical incision.

14. The Composix Kugel Mesh Patch was designed to fix the hernia by placing the patch on the inside of the abdominal wall, and therefore, the pressures of the body help to hold the patch in place over the hernia defect.

15. The Kugel Mesh line of products, invented by Dr. Robert D. Kugel, was first manufactured by Surgical Sense, Inc., starting in or around 1996. In January of 2000, Bard acquired the Kugel line of hernia repair products from Surgical Sense, Inc.

16. Defendants submitted their 510K Application for approval of the Composix Kugel Mesh Patch to the Federal Drug Administration (the "FDA") on January 22, 2001. Following the 510K Application, the patch was authorized by the FDA as a Class II medical device. Shortly thereafter, in 2001, Bard introduced the Composix Kugel Mesh Patch to the market through its wholly-owned subsidiary, Davol.

17. The Composix Kugel Mesh Patch is a two sided "dual mesh" prosthetic device developed to repair ventral (hernias of the abdominal region) and incisional hernias and was indicated by Defendants as an alternative to inguinal hernia repairs as well. The Composix Kugel Mesh Patch is inserted behind the hernia defect in the abdomen through a small incision. In order to fit through the small incision the mesh is folded in half. Once inside the abdomen the mesh re-deploys as a result of a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh.

18. The two sides of the Composix Kugel Mesh Patch are composed of two very different materials; with two very different purposes. Basically, the patch has a 'sticky' side and a 'slick' side. The sticky side is designed to face the abdominal wall and is composed of a double layer of Marlex™ (monofilament polypropylene or PPM). This fabric has a very high tissue

ingrowth factor - essentially making it like an adhesive. The 'slick' side of the patch is intended to face the bowels and is composed of expanded Teflon (ePTFE). This expanded Teflon fabric has a very low tissue ingrowth factor and is designed to shield the soft tissue of the bowels and other organs from the "sticky" Marlex" side of the Patch.

19. The inherently adhesive qualities of the Marlex side of the Composix Kugel Mesh Patch make it imperative that it never comes in contact with the bowels and other organs.

20. Due to the design and/or manufacturing defects present, this can occur when the mesh folds over on itself, the mesh wrinkles during placement or the mesh pulls away from the abdominal wall allowing bowel to loop and adhere to the 'sticky' side.

21. As a result, the mesh can: adhere (through tissue ingrowth) to vital organs and intestines; twist around the bowels and organs and cause strangulation and/or serious obstructions; cause necrosis of the organ tissue; become impossible to remove without also removing large portions of the bowel; develop infections; and lead to peritonitis, sepsis, organ shutdown and even death.

22. The plastic "memory recoil" ring in the Composix Kugel Mesh Patch was intended as a way to maintain integrity of the shape of the patch, and in doing so, keep the "sticky" side (Marlex™/PPM side) away from the sensitive organs and intestines.

23. Due to the design and/or manufacturing defects the memory recoil ring is prone to failure in several ways, including: pulling apart at the weld; breaking away from the weld; kinking, bending and folding directly across from the weld; and separating or tearing from patch material.

24. On information and belief, these defects and/or others were caused by multiple design and manufacturing errors and oversights, including but not limited to: failing to properly

test the weld strength of the rings; failing to run strength tests on the larger size rings; sewing lines damaging the ring during the manufacturing process and causing it to splinter or fracture; mesh shifting during sewing resulting in a 'shrunken' pocket causing the ring to buckle; the weld joint being placed at an incorrect location in the patch; and poor design and technique instruction by Defendants causing the physicians' staples and/or sutures to damage the ring during placement.

25. When the memory recoil ring malfunctions, numerous serious problems can occur, including:

a. the sharp/fractured PET plastic of the memory recoil ring can pierce the bowels or organs;

b. the ring can force its way through the abdominal wall and skin;

c. the ring can bend or break within the patch, causing it to lose its shape and forcing the "sticky" side onto the bowels and organs;

d. the ring can kink opposite the weld, pulling the patch away from the abdominal walls allowing the bowel to loop up and onto the "sticky" side; and

e. the ring can slide upon itself within the patch, pulling the patch into a ball or causing it to pull away from the abdominal wall.

f. the ring and/or the patch can otherwise fail to perform as intended, represented and/or designed.

26. The resulting injuries and damages from this ring failure include: fistulae created by the perforation of the bowels and other organs; perforation of the abdominal wall and skin; internal bleeding and necrosis of tissue; strangulation and/or serious obstructions of the bowels and organs; recurrence of hernias and prolonged hospitalizations; the necessity of removing large portions of the bowel; infections; and can lead to peritonitis, sepsis, organ shutdown, and even death.

27. Immediately after the Composix Kugel Mesh Patches were placed on the market, Defendants began receiving actual notices of memory ring failures as well as injuries stemming from Composix Kugel Mesh Patch defects.

28. Defendants actively and intentionally concealed this notice of the defective and dangerous condition associated with the Composix Kugel Mesh Patches from Plaintiff, Plaintiffs' physicians, the FDA, and the general public.

29. No later than 2003, Defendants uncovered serious problems with the weld process involving the memory recoil ring.

30. Despite attempts to correct the problem at the plant, Defendants found the corrective measures to be ineffective and the process still not in control.

31. Defendants were aware that these weld issues had existed from the time the Kugel Patches were originally placed on the market and all current lots suffered from this dangerous defect. Even the little information disclosed to date was intentionally withheld from Plaintiffs, Plaintiffs' physicians, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel Mesh Patches using the memory recoil ring.

32. As early as 2002, but after the defective and dangerous patch was already placed on the market, Defendants conducted physician screenings and reviews.

33. An Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time.

34. Whether intentionally or negligently, Defendants failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results.

35. These complaints and concerns of the physician surveyors were actively concealed by Defendants from Plaintiffs, Plaintiffs' surgeons, the FDA, and the public at large.

36. During the 2006 EIR, corporate executives informed the FDA that the spring and summer period of 2005 showed a marketed increase in the number of complaints with the Composix Kugel Mesh Patch.

37. In spite of their knowledge of increasing complaints and complications, Defendants waited until August 30, 2005 to initiate a partial Composix Kugel Mesh Patch distribution hold.

38. Even though Defendants realized the need for this distribution hold, they actively and intentionally chose not to immediately inform Plaintiffs, Plaintiffs' physicians, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel Mesh Patches of the problems and/or defects.

39. Defendants have since admitted that the product quality hold and release procedure was not applied on a timely basis.

40. As a result of this dangerous and defective condition, and the numerous serious injuries that have resulted, the FDA issued Class I recalls of the X-Large Oval, Large Oval and Large Circle varieties of the Composix Kugel Mesh Patch. A Class I recall is the highest level of recall available to the FDA. It is issued when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death.

41. On December 22, 2005 and January 13, 2006, Davol and Bard announced the recall of the Composix Kugel Mesh X-Large patch. Subsequently, in March of 2006, the Defendants announced the recall of the Composix Kugel Mesh Large Patch as well.

42. Under these FDA recalls, the following products were subject to recall:

PC#0010206	Bard Composix Kugel	Extra Large Oval	8.7" x 10.7"
PC#0010207	Bard Composix Kugel	Extra Large Oval	10.8" x 13.7"
PC#0010208	Bard Composix Kugel	Extra Large Oval	7.7" x 9.7"
PC#0010209	Bard Composix Kugel	Large Oval	6.3" x 12.3"
PC#0010202	Bard Composix Kugel	Large Oval	5.4" x 7"
PC#0010204	Bard Composix Kugel	Large Circle	4.5"

43. Then, on January 10, 2007, Davol and Bard expanded the recall to include all Composix Kugel Mesh Large Oval and Large Circle Mesh patches, as well as all products manufactured from January 2004 to January 2006, that had the same component design as the recalled manufacturing lots.

44. Upon information and belief, it is possible that additional Composix Kugel Mesh Patches will experience the same defects as the currently recalled models and will need to be recalled as well.

45. The FDA conducted the aforementioned EIR investigations in January and February of 2006. Upon information and belief, the results of these investigations determined, among other things, that Defendants:

a. had excluded ring failure events which should have been included from their complication database, reports, and recall notices;

b. misidentified numerous Composix Kugel Mesh Patch complication events;

c. failed to apply the product quality hold and release procedure on a timely basis;

d. failed to properly follow the procedures for conducting design validation review;

e. failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Composix Kugel Mesh Patch complications; specifically, they provided no justification for including only the Extra Large Composix Kugel Mesh Patch sizes in the December 2005 recall;

f. failed to provide full information which they knew regarding numerous Composix Kugel Mesh Patch complaints;

g. failed to actually perform strength testing on memory recoil rings for all sizes of Composix Kugel Mesh Patch before putting them into the stream of commerce;

h. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the ring failures and Composix Kugel Mesh Patch complaints resulting in numerous inconsistencies and errors in the raw data and from the actual complaints and what was placed in the electronic databases;

i. failed to establish and implement procedures to ensure that the device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality System regulation; and

j. failed to ensure that devices conform to defined user/patient needs and intended uses.

46. Additionally, upon information and belief, the ring break issue with the Composix Kugel Mesh Patch was not brought to the FDA's attention until over 20 months after Defendants knew of the first death resulting from their products.

47. Despite the serious risk of injury (and even death) resulting from the Composix Kugel Mesh Patch, Defendants took woefully insufficient steps to notify Plaintiffs of the patches' defects.

48. Evidence shows that Defendants held back on implementing a full recall - and actively notifying patients of the recall - until over a year after the first recall was issued. In fact, evidence shows that for a period of time after the recall was issued Defendants informed doctors that because this was a "voluntary" recall, patients need not be notified at all.

49. Upon information and belief, Defendants claimed during their expanded recall that there had only been 28 reported ring breaks. Many of which were years before the first

recall. In actuality, at least 85 ring breaks had been reported. Defendants only told the FDA about the ring breaks which they confirmed by getting the samples returned. Upon information and belief, if the sample was not returned, Defendants minimized the seriousness of the report and intentionally chose not to include the complaint when providing their statistical analysis to the FDA.

50. Upon information and belief, as of January 2007, roughly 100,000 Composix Kugel Mesh Patches had been sold. Upon information and belief, the vast majority of the patches which have been implanted are currently still inside patients residing in the United States.

GENERAL ALLEGATIONS

51. The Composix Kugel Mesh Patches present and constitute an unreasonable risk of danger and injury in the following respects:

a. the memory recoil ring of the Composix Kugel Mesh Patch is likely to malfunction during, or after, it is implanted;

b. the Composix Kugel Mesh Patch was not properly manufactured;

c. the Composix Kugel Mesh Patch was defectively designed;

d. the Composix Kugel Mesh Patch did not perform as safely as an ordinary consumer/patient would expect;

e. the Composix Kugel Mesh Patch was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and/or

f. such further and additional defects as discovery and the evidence reveal.

52. At all times relevant, Defendants were engaged in the design, manufacturing, assembling, distributing, conveying and/or selling of the Composix Kugel Mesh Patch in their ordinary course of business. Defendants designed, manufactured, assembled and sold the devices

to hospitals and physicians, knowing that they would be thereby sold to patients who needed hernia repair surgery, including Plaintiff.

53. Defendants' Composix Kugel Mesh Patches are uniformly defective because they possess the same potential for breakage or malfunction of the memory recoil ring and, as a result, are subject to risk of resulting injury.

54. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.

55. Defendants did not have adequate and appropriate systems in place, or did not apply those systems, to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the Composix Kugel Mesh Hernia Patches, as required by the U.S. Food & Drug Administration ("FDA"), thus leading to inconsistencies and irregularities in the way Defendants kept track of complaints they received regarding the failure of the Composix Kugel Mesh Patches.

56. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, of the seriousness of the risk of using the Composix Kugel Mesh Patch based upon the state of knowledge of the patch as it existed at the time, and upon generally accepted medical and research standards and principles.

57. Upon information and belief, Defendants failed to send the necessary product failure reports to the FDA, indicating that the Composix Kugel Mesh Patch was causing serious and fatal injuries in persons who used the patch.

58. Upon information and belief, Defendants misrepresented the known risks inherent in the use of the Composix Kugel Mesh Patch.

59. Defendants did not timely apprise the Plaintiff, the FDA, physicians and general public of the defect in their Composix Kugel Mesh Patches, despite Defendants' knowledge that memory recoil rings had failed due to the described defects. Defendants' concealment of a known defect from Plaintiffs equitably tolls any applicable statutes of limitation.

60. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

61. Upon information and belief, the purpose of Defendants' conduct, directed at patients, physicians and consumers, was to create demand for and sell the Composix Kugel Mesh Patches. Each aspect of Defendants' conduct combined to artificially create sales of the Composix Kugel Mesh Patches.

62. As a direct and proximate cause of cumulative and indivisible nature of Defendants' conduct and the recalled Composix Kugel Mesh Patches, Plaintiffs have suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiffs have incurred and will continue to incur damages related to the recalled Composix Kugel Mesh Patches.

COUNT I
(Negligence and Negligence Per Se)

63. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

64. At all times herein mentioned Defendants had a duty to exercise reasonable care in the course of its design, manufacture, sale, testing, marketing, advertising, promoting,

distribution and warning about the Composix Kugel Mesh Patch. This duty included, among other things, to assure that the products did not cause users to suffer from unreasonable and dangerous side-effects and to warn Plaintiffs of the defective nature of Defendants' devices. Defendants breached their duty of reasonable care to Plaintiffs by incorporating a defect into the design of the devices, thereby causing injuries to Plaintiff.

65. At all times herein mentioned Defendants had an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the recalled Composix Kugel Mesh Patch.

66. Defendants' actions were violations of statutes, ordinances and/or rules and regulations, constituting negligence per se.

67. At all times relevant, Defendants knew, or in the exercise of reasonable care should have known, that the Composix Kugel Mesh Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, and were unreasonably likely to injure the products' users.

68. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the aforesaid products, that they were dangerous and unsafe for the use and purpose for which they were intended.

69. Defendants knew, or should have known, that consumers such as Plaintiffs could foreseeably suffer injuries as a result of Defendants' failure to exercise ordinary care.

70. Defendants breached their duty of reasonable care to Plaintiff, including but not limited to the following negligent acts and/or omissions:

a. manufacturing, producing, promoting, formulating, creating and/or designing the Composix Kugel Mesh Patch without thoroughly and adequately testing it;

b. failing to conduct sufficient testing programs to determine whether or not the aforesaid Composix Kugel Mesh Patch was safe for use; in that Defendants knew or should have known that the Composix Kugel Mesh Patch was unsafe and unfit for use by reason of the dangers to its users;

c. selling the Composix Kugel Mesh Patch without making proper and sufficient tests to determine the dangers to its users;

d. failing to adequately and correctly warn Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of the Composix Kugel Mesh Patch;

e. failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the Composix Kugel Mesh Patch;

f. negligently advertising and recommending the use of the Composix Kugel Mesh Patch without sufficient knowledge as to its dangerous propensities;

g. negligently representing that the Composix Kugel Mesh Patch was safe for use for their intended purpose, when, in fact, it was unsafe;

h. negligently designing the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

i. negligently manufacturing the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

j. negligently producing the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

k. negligently assembling the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

l. improperly concealing information concerning FDA warnings from the Plaintiff, healthcare professionals, and/or the FDA in knowing that the

Composix Kugel Mesh Patch was unsafe, dangerous, and/or non-conforming with FDA regulations.

m. violating statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

71. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Composix Kugel Mesh Patch in that they:

a. failed to use due care in designing and manufacturing the Composix Kugel Mesh Patch so as to avoid the aforementioned risks to individuals when the Composix Kugel Mesh Patch was used to repair ventral and incisional hernias;

b. failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the Composix Kugel Mesh Patch;

c. failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the Composix Kugel Mesh Patch;

d. failed to warn Plaintiffs of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

e. failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Composix Kugel Mesh Patch;

f. failed to warn Plaintiffs prior to actively encouraging the sale of the Composix Kugel Mesh Patch, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and/or

g. were otherwise careless or negligent.

72. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

73. As a direct and proximate result of the carelessness and negligence of Defendants, as set forth in the preceding paragraphs, Plaintiffs have sustained and will continue to sustain damages, and is therefore entitled to compensatory and other damages, and equitable, injunctive, and declaratory relief according to proof.

COUNT II
(Products Liability - Failure to Warn)

74. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

75. Defendants are manufacturers and/or sellers of the Composix Kugel Mesh Patch.

76. The Composix Kugel Mesh Patches manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have know of the risk of injury from the product, they failed to provide adequate warnings to users or consumers of the product and continued to promote the products aggressively.

77. The Composix Kugel Mesh Patches manufactured and/or supplied by Defendants were unaccompanied by proper warnings regarding all possible adverse side-effects or results associated with the design, manufacturing, implantation and/or use of the Composix Kugel Mesh Patch.

78. Defendants failed to warn the FDA of material facts regarding the safety and efficacy of the Composix Kugel Mesh Patch, such that this medical device would never have been approved, and no physician would have been able to use them as a hernia repair tool in the United States.

79. Defendants failed to warn consumers and physicians of material facts regarding the safety and efficacy of the Composix Kugel Mesh Patch

80. Defendants failed to perform adequate testing. Adequate testing would have shown that the Composix Kugel Mesh Patches possess design and manufacturing flaws resulting in serious potential side effects and health risks. Full and proper warnings with respect to these results should have been made.

81. As the producing cause and legal result of the defective condition of the Composix Kugel Mesh Patch as manufactured and/or supplied by Defendants, and as a direct and proximate result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:

a. Plaintiffs have suffered significant physical injury and are at an increased risk of contracting a serious latent injury;

b. Plaintiffs have sustained economic loss including purchase price, the cost of medical tests and services, hospital costs, and other costs incidental to the implantation and monitoring of a harmful and defective product into his body; and

c. Plaintiffs require reasonable and necessary health care, attention and services to test for and monitor the onset of serious injury resulting from Defendants' product.

COUNT III
(Products Liability - Defective Design and/or Defective Manufacture)

82. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

83. The Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective in design or manufacturing in that, when they left the hands of the manufacturer and/or supplier, they were unreasonably dangerous because they were more dangerous than an ordinary consumer would expect and more dangerous other methods of hernia repair.

84. Alternatively, the Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective in design or manufacturing in that, when they left the hands of the

manufacturer and/or supplier, the foreseeable risks exceeded the benefits associated with the design.

85. The Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective due to inadequate warning or instruction because Defendants knew or should have known that the product created a risk of harm to consumers and Defendants failed to adequately warn of those risks.

86. The Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective due to inadequate testing.

87. The Composix Kugel Mesh Patch manufactured and/or sold by Defendants were defective due to inadequate post-marketing warning or instruction because, after the manufacturer knew or should have known that the product created a risk of harm to consumers and Defendants failed to adequately warn of those risks and continued to promote the product.

88. As the producing cause and legal result of the defective condition of the Composix Kugel Mesh Patch as manufactured and/or supplied by Defendants, and as a direct and proximate result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:

a. Plaintiffs have suffered significant physical injury and is at increased risk of contracting a serious latent injury;

b. Plaintiffs have sustained economic loss including purchase price, the cost of medical tests and services, hospital costs, and other costs incidental to the implantation and monitoring of a harmful and defective product into his body; and

c. Plaintiffs require reasonable and necessary health care, attention and services to test for and monitor the onset of serious injury resulting from Defendants' product.

COUNT IV
(Violation of Consumer Protection Statutes)

89. Plaintiffs re-allege the allegations contained in the foregoing paragraphs.

90. Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the defective patches.

91. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for the defective patches, and would not have incurred related medical costs and injury.

92. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiffs for the defective patches that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

93. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the defective patches. Each aspect of Defendants' conduct combined to artificially create sales of the defective patches.

94. Defendants are liable to Plaintiffs jointly and severally for all general, special and injunctive relief to which Plaintiffs are entitled by law. Under statutes enacted in Rhode Island, Minnesota, and New Jersey and to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Plaintiffs are consumers who purchased a Kugel Mesh Patch pursuant to a consumer transaction for personal use and is therefore subject to protection under such legislation.

95. Under statutes enacted in Rhode Island, Minnesota, and New Jersey to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendant is the supplier, manufacturer, advertiser, and seller, who is

subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

96. Defendants violated the statutes enacted in Rhode Island, Minnesota, and New Jersey to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the leads were fit to be used for the purpose for which they were intended, when in fact the leads were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

97. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in Rhode Island, Minnesota, and New Jersey to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

98. Defendants had actual knowledge of the defective and dangerous condition of the Kugel Mesh Patch, and failed to take any action to cure such defective and dangerous conditions.

99. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which cardiac device to utilize.

100. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq., Minn. Stat. §§ 325D.43, et seq., 325F.67, et seq., 325F.68 et seq., and N.J. Rev. Stat. § 56:8-1 et seq.

101. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable loss and damages.

102. As a direct and proximate result of Defendants' violations of R.I. Gen. Laws § 6-13.1-1, et seq., Minn. Stat. §§ 325D.43, et seq., 325F.67, et seq., 325F.68 et seq., and N.J. Rev. Stat. § 56:8-1 et seq., Plaintiffs have sustained economic losses and other damages and is entitled to statutory, compensatory, injunctive and declaratory relief in an amount to be proven at trial.

COUNT V
(Violation Of Minnesota False Statements In Advertising Act)

103. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

104. Defendants produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Kugel Mesh Patch after learning of their inherent defects with the intent to sell the Kugel Mesh Patch.

105. Defendants concealed their deceptive practices in order to increase the sale of and profit from the Kugel Mesh Patch.

106. Defendants violated the Minnesota False Statements in Advertising Act, Minn. Stat. § 325F.67 et seq., when they failed to comply with FDA requirements and when they failed to adequately warn consumers and the medical community of the safety risks associated with the Kugel Mesh Patch.

107. Defendants violated Minn. Stat. § 325F.67 by intending to sell and create customer demand for the Kugel Mesh Patch by using deceptive or untrue statements of fact about the Kugel Mesh Patch's mechanical soundness and the reliability of the leads through promotional materials, including but not limited to, Defendants' website and medical brochures distributed to patients and physicians.

108. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 et seq., Plaintiffs were injured in that they paid substantial sums for the Kugel Mesh Patch and for the costs of replacing the Kugel Mesh Patch that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

109. The Minnesota False Statement in Advertising Act applies to Plaintiff's transactions with Defendants because Defendants deceptive scheme was carried out in Minnesota and affected Plaintiffs implanted with the defective Kugel Mesh Patch.

110. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have also sustained and will continue to sustain severe physical injuries and/or death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory, injunctive, equitable, and declaratory relief in an amount to be proven at trial.

COUNT VI
(Violation Of The Minnesota Deceptive Trade Practice Act)

111. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

112. Defendants applied advertising and marketing campaigns representing the Kugel Mesh Patch as mechanically sound and medically safe, while Defendants knew of the defects in the Kugel Mesh Patch. Defendants continued these campaigns of deception until 2007, when the Kugel Mesh Patches were recalled.

113. Defendants knew or should have known of the defective nature of the Kugel Mesh Patch but denied public access to the information, to avoid corporate responsibility.

Defendants knew the Plaintiffs and their physicians were at a disadvantage in accessing information involving the safety of the Kugel Mesh Patch.

114. Defendants concealed the defects of the Kugel Mesh Patch for the purposes of higher profits and increased sales.

115. Defendants have violated Minn. Stat. §325D.44. The violations include the following:

(a) Defendants violated Minn. Stat. §325D.44 (5) by representing the Kugel Mesh Patch as having characteristics, uses, and benefits of a safe and mechanically sound device while knowing the statements were false and the Kugel Mesh Patch contained inherent defects, including manufacturing defects;

(b) Defendants violated Minn. Stat. § 325D.44 (7) by representing the Kugel Mesh Patch as a non-defective medical product of a particular standard, quality, or grade while knowing the statements were false and the Kugel Mesh Patch contained inherent defects, including manufacturing defects;

(c) Defendants violated Minn. Stat. § 325D.44 (9) by advertising, marketing, and selling the Kugel Mesh Patch as medically reliable and without a known design defect while knowing those claims were false and without any medical support; and

(d) Defendants violated Minn. Stat. § 325D.44 (13) by creating a likelihood of confusion about the efficacy and mechanical soundness of the Kugel Mesh Patch, comparing the Kugel Mesh Patch with other non-defective products.

116. The Minnesota statutes prohibiting unfair and deceptive trade practices apply because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs who were implanted with the Kugel Mesh Patch containing the known defects.

117. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory, injunctive, equitable and declaratory relief in an amount to be proven at trial.

COUNT VII
(Violation Of The Minnesota Prevention Of Consumer Fraud Act)

118. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

119. Defendants intentionally concealed their design and manufacturing defects and failed to disclose the defects for the purpose of continuing to sell and distribute the Kugel Mesh Patch.

120. Defendants represented that the Kugel Mesh Patches were safe and effective and intended that Plaintiffs and their physicians rely on those representations when deciding if Defendants' Kugel Mesh Patches were optimal for meeting the Plaintiff's needs.

121. Through these misleading and deceptive statements and false promises, Defendants violated Minn. Stat. § 325F.69.

122. The Minnesota statutes prohibiting consumer fraud apply to all of Defendants' transactions with Plaintiffs implanted with the Kugel Mesh Patch because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs implanted with defective Kugel Mesh Patch.

123. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory, injunctive, equitable, and declaratory relief in an amount to be proven at trial.

COUNT VIII
(Breach of Express Warranty)

124. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

125. Defendants' concealment and failure to warn through promotional statements and product literature expressly warranted that the Composix Kugel Mesh Patch was safe and/or well accepted by users.

126. The Composix Kugel Mesh Patch does not conform to these express representations because the Composix Kugel Mesh Patch is not safe and have numerous serious risks and side effects.

127. Defendants breached the aforesaid express warranties, as their Composix Kugel Mesh Patches were defective.

128. Defendants expressly represented to the users, their physicians, healthcare providers, and the FDA that the Composix Kugel Mesh Patch was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

129. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Composix Kugel Mesh Patch was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

130. As a direct and proximate result of the breach of said warranties, Plaintiffs suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

131. Defendants expected, or reasonably should have expected, members of the medical community, including physicians and/or other healthcare professionals, to rely upon the representations and warranties of the Defendants for use of the Composix Kugel Mesh Patch.

132. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received the Composix Kugel Mesh Patches, including Plaintiff, are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and such other side effects as serious infection. They also face the need for additional surgery to remove or replace the defective product, the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences as a result of the defective, unsafe and recalled product they received.

133. As a result of the foregoing acts and omissions, Plaintiffs have suffered damages and will incur medical, health, incidental and related expenses now and in the future.

COUNT IX
(Breach of Implied Warranty)

134. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

135. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the Composix Kugel Mesh Patch, which is used for repairing ventral and incisional hernias.

136. At the time Defendants marketed, sold, and distributed the Composix Kugel Mesh Patch for use by Plaintiff, Defendants knew of the use for which the Composix Kugel Mesh Patch was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

137. Defendants impliedly represented and warranted to the users and their physicians, healthcare providers, and the FDA that the Composix Kugel Mesh Patch was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

138. That said representations and warranties aforementioned were false, misleading, and inaccurate in that the Composix Kugel Mesh Patch was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

139. The Composix Kugel Mesh Patch was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

140. Defendant breached the aforesaid implied warranties, as their Composix Kugel Mesh Patch were not fit for their intended purposes and uses. Plaintiffs are hernia repair surgery patients who had the Composix Kugel Mesh Patch surgically implanted in their bodies. As such, Defendants expected, or reasonably should have expected, Plaintiffs to use or be affected by the Composix Kugel Mesh Patch.

141. As a result of the defective nature of the Composix Kugel Mesh Patch, Plaintiffs are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and such other side effects as serious infection. Plaintiffs also face the need for additional surgery to remove or

replace the defective product, the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences as a result of the defective, unsafe and recalled product they received.

142. As a result of the foregoing acts and omissions, the Plaintiffs have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now and in the future.

COUNT X
(Unjust Enrichment)

143. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

144. Defendants have financially benefited and been enriched by the unlawful and inequitable conduct alleged herein. Defendants have reaped enormous benefits and profits from consumers as a result of the sale of these defective and unreasonably dangerous devices.

145. Defendants have knowledge of this benefit.

146. Defendants have voluntarily accepted and retained this benefit, to the economic detriment of Plaintiff.

147. The circumstances, described herein, are such that it would be inequitable for Defendants to retain the ill-gotten benefit without paying the value thereof to Plaintiff.

148. Plaintiffs are entitled to the amount of Defendants' ill-gotten gains, including interest, resulting from its unlawful, unjust, unfair and inequitable conduct in manufacturing, marketing, promoting and selling its Composix Kugel Mesh Patch products.

COUNT XI
(Fraud and Deceit)

149. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

150. Defendants conducted research and used the Composix Kugel Mesh Patch as part of their research.

151. As a result of Defendants' research and testing, or lack thereof, Defendants distributed blatantly and intentionally false information, including but not limited to assuring the public, the Plaintiff, his doctors, hospitals, healthcare professionals, and/or the FDA that the Composix Kugel Mesh Patch was safe to use as a means of repairing ventral and incisional hernias.

152. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

153. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

154. The information distributed to the public, the FDA and the Plaintiff, by Defendants, including but not limited to reports and press releases, contained material representations of fact and/or admissions.

155. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' Composix Kugel Mesh Patch was safe for use in repairing ventral and incisional hernias.

156. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that the Composix Kugel Mesh Patch was not injurious to the health and/or safety of its intended users. These representations were false and misleading.

157. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that the Composix Kugel Mesh Patch was not safe as a means of repairing ventral and incisional hernias.

158. Defendants intentionally made material representations to the FDA and the public, including the medical profession, the Plaintiff, regarding the safety of the Composix Kugel Mesh Patch, specifically but not limited to the Composix Kugel Mesh Patch not having dangerous and serious health and/or safety concerns.

159. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and the Plaintiff, to gain the confidence of the public, the FDA, and the Plaintiff, to falsely ensure the quality and fitness for use of the Composix Kugel Mesh Patch and induce the public, and the Plaintiffs to use the Composix Kugel Mesh Patch.

160. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, the FDA, and the Plaintiff, that Composix Kugel Mesh Patch was fit and safe for use in repairing ventral and incisional hernias.

161. That Defendants made claims and representations in the documents submitted to the FDA, to the public, and the Plaintiff, that the Composix Kugel Mesh Patch did not present serious health and/or safety risks.

162. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

163. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, and were made in order to induce the Plaintiffs to rely upon misrepresentations and caused the Plaintiffs to use and rely on the Composix Kugel Mesh Patch.

164. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of the Composix Kugel Mesh Patch to the public at large, the Plaintiffs in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective.

165. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of the Composix Kugel Mesh Patch by concealing the suppressing material facts regarding the dangerous and serious health and/or safety concerns of the Composix Kugel Mesh Patch.

166. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiffs into a sense of security so that Plaintiffs would rely on the representations and purchase, use, and rely on the Composix Kugel Mesh Patch and/or that their respective healthcare providers would do the same.

167. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public,

including the Plaintiffs and/or their respective healthcare provider, would rely upon the information being disseminated.

168. That the Plaintiffs did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of hernia repair patches, and were thereby induced to purchase, use and rely on Defendants' Composix Kugel Mesh Patch.

169. That at the time the representations were made, the Plaintiffs did not know the truth with regard to the dangerous and serious health and/or safety concerns of the Composix Kugel Mesh Patch.

170. That the Plaintiffs did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiffs with reasonable diligence have discovered the true facts.

171. That had Plaintiffs known the true facts with respect to the dangerous and serious health and/or safety concerns of the Composix Kugel Mesh Patch, Plaintiffs would not have used and/or relied on Defendants' Composix Kugel Mesh Patch.

172. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly, and/or purposefully on the Plaintiff.

173. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received and/or rely on the Composix Kugel Mesh Patch have suffered and/or are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and/or such other side effects as serious infection, the need for additional surgery to remove and/or replace the defective product, and/or the need for subsequent surgery to repair perforations caused by the

defective product, as well as other severe and permanent health consequences and/or medical monitoring as a result of the defective, unsafe and recalled product they received.

174. As a result of the foregoing acts and omissions, the Plaintiffs have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now or in the future.

COUNT XII
(Negligent Misrepresentation)

175. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

176. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, the Composix Kugel Mesh Patch, had been tested and found to be safe and effective for repairing ventral and incisional hernias. The representations made by Defendants were, in fact, false.

177. Defendants failed to exercise ordinary care in the representation of the Composix Kugel Mesh Patch, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented the Composix Kugel Mesh Patch's high risk of unreasonable, dangerous side effects.

178. Defendants breached their duty in representing the Composix Kugel Mesh Patch's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and/or the public in general.

179. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received and/or rely on the Composix Kugel Mesh Patch have suffered and/or are at an increased risk of suffering serious and dangerous side effects, including but not limited to

bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and/or such other side effects as serious infection, the need for additional surgery to remove and/or replace the defective product, and/or the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences and/or medical monitoring as a result of the defective, unsafe and recalled product they received.

180. As a result of the foregoing acts and omissions, the Plaintiffs have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now or in the future.

COUNT XIII
(Fraudulent Misrepresentation)

181. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

182. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, the FDA, and the public in general, that said product, the Composix Kugel Mesh Patch, had been tested and found to be safe and effective for its intended use in repairing ventral and incisional hernias. The representations made by Defendants were, in fact, false.

183. When said representations were made by Defendants, it knew the representations to be false, and it willfully, wantonly and recklessly disregarded whether the representations were true.

184. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend and use said product, the Composix Kugel

Mesh Patch, in repairing ventral and incisional hernias, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiffs herein.

185. At the time the aforesaid representations were made by the Defendants and, at the time that the Plaintiffs used the Composix Kugel Mesh Patch, the Plaintiffs were unaware of the falsity of said representations and reasonably believed them to be true.

186. In reliance upon said representations, the Plaintiffs were induced to and did use the Composix Kugel Mesh Patch, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

187. Defendants knew and were aware or should have known that the Composix Kugel Mesh Patch had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

188. Defendants knew or should have known that the Composix Kugel Mesh Patch had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous.

189. Defendants brought the Composix Kugel Mesh Patch to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

190. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received and/or rely on the Composix Kugel Mesh Patch have suffered and/or are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and/or such other side effects as serious infection, the need for additional surgery to remove and/or replace the defective product, and/or the need for subsequent surgery to repair perforations caused by the

defective product, as well as other severe and permanent health consequences and/or medical monitoring as a result of the defective, unsafe and recalled product they received.

191. As a result of the foregoing acts and omissions, the Plaintiffs have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now or in the future.

COUNT XIV
(Fraudulent Concealment)

192. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

193. At all times during the course of dealing between Defendants and Plaintiff, Defendants misrepresented that the Composix Kugel Mesh Patch was safe for its intended use.

194. Defendants knew or were reckless in not knowing that its representations were false.

195. In representations to Plaintiff, the FDA and/or healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that the Composix Kugel Mesh Patch was not safe for repairing ventral and incisional hernias;

b. that the risk of serious injury and side effects with the Composix Kugel Mesh Patch were not adequately tested by Defendants;

c. that Defendants were aware of dangers with the Composix Kugel Mesh Patch;

d. that the Composix Kugel Mesh Patch was defective, and that it caused dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death and/or serious infections, as well as other severe and permanent health consequences;

e. that patients needed to be monitored more regularly than normal while using the Composix Kugel Mesh Patch;

f. that the Composix Kugel Mesh Patch was manufactured negligently and defectively;

g. that the Composix Kugel Mesh Patch was manufactured improperly; and

h. that the Composix Kugel Mesh Patch was designed negligently, defectively and improperly.

196. Defendants were under a duty to disclose to Plaintiffs and their physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Composix Kugel Mesh Patch.

197. Defendants had sole access to material facts concerning the defective nature of the Composix Kugel Mesh Patch and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Composix Kugel Mesh Patch, including the Plaintiff.

198. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the Composix Kugel Mesh Patch was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and his physicians, hospitals and/or healthcare providers into reliance on and use of the Composix Kugel Mesh Patch.

199. Defendants knew that Plaintiff, and his physicians, hospitals, healthcare providers, and the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the Composix Kugel Mesh Patch, as set forth herein.

200. Plaintiff, as well as his doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposely did not include facts that were concealed and/or omitted by Defendants.

201. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received and/or rely on the Composix Kugel Mesh Patch have suffered and/or are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and/or such other side effects as serious infection, the need for additional surgery to remove and/or replace the defective product, and/or the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences and/or medical monitoring as a result of the defective, unsafe and recalled product they received.

202. As a result of the foregoing acts and omissions, the Plaintiffs have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now or in the future.

COUNT XV
(Medical Monitoring)

203. Plaintiffs re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

204. Plaintiffs have been significantly exposed to a hazardous product through the tortuous conduct of Defendants. As a direct and proximate result of that exposure, Plaintiffs have suffered an increased risk of incurring serious latent injury relative to individuals who do not have Defendants' mesh product surgically implanted in his body. This increased risk of injury makes it reasonably necessary for Plaintiffs to undergo periodic diagnostic medical examinations different from what would be prescribed in absence of the exposure to Defendants' defective device. As such, medical monitoring is necessary and reasonably certain to be incurred as a proximate result of Defendants' conduct.

205. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have incurred and will likely continue to incur medical costs relating to the Composix Kugel Mesh Patch, including medical monitoring and/or other hospital costs, in an amount to be proven at trial. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs are entitled to injunctive relief in the form of a court supervised medical monitoring program.

206. Medical monitoring is medically reasonable and necessary in order to provide for the early detection and prevention of irreparable harm, sever and debilitating injuries and death. In the absence of such relief, Plaintiffs might not receive prompt medical care that could prolong his productive life, increase prospects for improvement and minimize disability.

207. Medical testing and monitoring procedures are currently available, including but not limited to CT Scans, to determine whether any problems have developed due to the implanted mesh patch. In fact, upon information and belief, doctors and hospitals have already began creating an implementing their own medical monitoring programs - to address this real and dangerous problem.

COUNT XVI
(Loss Of Consortium)

208. Plaintiffs re-allege the allegations contained in the foregoing paragraphs.

209. Plaintiff Marcelo Vega was at all times relevant hereto the spouse of Plaintiff Mary Vega, and lived and cohabited with her.

210. Plaintiff Marcelo Vega has necessarily paid and has become liable to pay for medical aid, treatment and for medications and other expenses associated with Plaintiff's injuries.

211. Plaintiff Marcelo Vega has been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society, and the ability of Plaintiff, has in those

respects been impaired and depreciated, and the marital association between husband and wife has been altered and, accordingly, has been caused great mental anguish.

212. Accordingly, Plaintiffs seek and are entitled to compensatory and other damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

1. For an Order establishing a medical monitoring program with a trust fund that is funded by Defendants and under the jurisdiction and supervision of the Court, to provide medical testing, screening, services, research and education and a medical/legal registry to ensure that Plaintiffs receives prompt and proper medical treatment;

2. For compensatory damages;

3. For all applicable statutory damages under the consumer protection legislation;

4. For an award of treble damages where available;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest and the costs of suit; and

7. For such other and further relief as this court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury in this case on all counts so triable.

Dated: December 3, 2008

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

Robert K. Shelquist (21310X)
Yvonne M. Flaherty (267600)
100 Washington Avenue South, Suite 2200
Minneapolis, Minnesota 55401-2197
Telephone: 612-339-6900
Facsimile: 612-339-0981
Attorneys for Plaintiff

S 93424

LOCKRIDGE GRINDAL NAUEN
P.L.L.P.
Attorneys at Law

www.locklaw.com

MINNEAPOLIS
Suite 2200
100 Washington Avenue South
Minneapolis, MN 55401-2179
T 612.339.6900
F 612.339.0981

WASHINGTON, D.C.
Suite 210
415 Second Street, N.E.
Washington, DC 20002-4900
T 202.544.9840
F 202.544.9850

Yvonne M. Flaherty
Phone: 612-339-6900
ymflaherty@locklaw.com
REPLY TO MINNEAPOLIS

December 3, 2008

VIA MESSENGER
Clerk of Court
U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

Re: *Mary Vega v. Davol, Inc., et al.*

Dear Clerk of Court:

Enclosed for filing in the above-referenced matter is a Summons, Complaint, and Civil Cover Sheet. I have also enclosed a check in the amount of $350.00 in payment of the filing fee.

Please sign the Summons, file-stamp the copy of the Complaint and return to the messenger for return to my office.

If you have any questions, please feel free to contact me.

Very truly yours,

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

Yvonne M. Flaherty

YMF/brg
Enclosures